AUG 2 5 2011

510(k) Summary

K112104

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

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317-521-3501

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Date Prepared: July 15, 2011

Device Name

Proprietary name: Elecsys N-MID Osteocalcin CalCheck 5
Common name: Osteocalcin CalCheck 5
Classification name: Single (specified) analyte controls (assayed and unassayed)

Predicate device

The Elecsys N-MID Osteocalcin CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the cleared Elecsys DHEA-S CalCheck 5 (K103402).

Device Description

The Elecsys N-MID Osteocalcin CalCheck 5 is a lyophilized product consisting of synthetic osteocalcin in a human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Intended use

The Elecsys N-MID Osteocalcin CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys N-MID Osteocalcin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

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Comparison Table The table below compares Elecsys N-MID Osteocalcin CalCheck 5 with the predicate device, Elecsys DHEA-S CalCheck 5 (K103402).

Characteristic	Elecsys N-MID Osteocalcin CalCheck 5 (Candidate Device)	Elecsys DHEA-S CalCheck 5 (K103402)
	Differences	
Intended Use	The Elecsys N-MID Osteocalcin CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys N-MID Osteocalcin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.	The Elecsys DHEA-S CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys DHEA-S reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.
Stability	Reconstituted: • 20-25°C: 5 hours	Reconstituted: • 20-25°C: 4 hours
Analyte	Osteocalcin	DHEA-S
	Similarities	
Levels	Five	Same
Format	Lyophilized	Same
Handling	Reconstitute Check 1, Check 2, Check 3, Check 4, and Check 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.	Same
Matrix	Human serum matrix	Same
Stability	Unopened: • Store at 2-8°C until expiration date	Unopened: • Same

Performance Characteristics The Elecsys N-MID Osteocalcin CalCheck 5 was evaluated for value assignment and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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Roche Diagnostics
c/o Ms. Jane Ellen Phillips
Program Manager, Regulatory Submissions
9115 Hague Road
P.O. Box 50416
Indianapolis, IN 46250

Re: k112104
Trade Name: Elecsys N-MID Osteocalcin CalCheck 5
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: Class I, reserved
Product Codes: JJX
Dated: July 21, 2011
Received: July 22, 2011

Dear Ms. Phillips,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

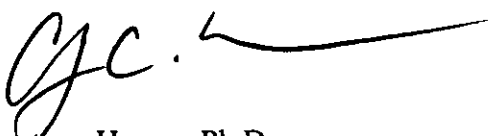
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k112104

Device Name: Elecsys N-MID Osteocalcin CalCheck 5

Indications for Use:

The Elecsys N-MID Osteocalcin CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys N-MID Osteocalcin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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